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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/660,370	09/11/2003	James Stephen Shaw	1662.009US2	5456

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EXAMINER	
WESSENDORF, TERESA D	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 08/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/660,370	SHAW, JAMES STEPHEN	
	Examiner	Art Unit	
	T. D. Wessendorf	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-68* is/are pending in the application.

4a) Of the above claim(s) *1-40,43-47,49-53 and 56-68* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *41,42,48,54 and 55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group V (claims 41-55) is acknowledged. Applicant's election with traverse of the species Seq. ID. No. 320 is also acknowledged. Applicant states that as provided by the MPEP, species may be related inventions and need not be subject to restriction. See MPEP 806.04(b). In particular, where species are claimed under a common genus and are related, the question of restriction is determined by the practice applicable to election of species and the practice applicable to other types of restrictions. See id. Applicants also respectfully remind the Examiner that they are entitled to examination of a reasonable number of species, and that election of species is for the convenience of the Examiner in initiating the search. Here, at least claim 41 is generic with regard to the phosphorylated peptides. This generic claim explicitly defines how the claimed species are related - all phosphorylated peptides recognized by binding entities. Moreover, as detailed in the application, each peptide is susceptible to phosphorylation by the human kinase PKc-theta and each corresponds in structure to a human proteomic sequence following phosphorylation by PKc-theta. The Examiner is reminded that M.P.E.P. 803.02 states that if the members of the Markush

group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the Examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. In such a case, the Examiner will not . . . require restriction. Should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended . . . to the extent necessary to determine patentability of the Markush-type claim.'' (Emphasis added.) Applicant requests reconsideration of the requirement for election of a species. If this request is denied, Applicant notes that during a telephone conversation on May 17, 2005, the Examiner agreed that, as required under M.P.E.P. j 803.02, additional species would be examined if a search of the elected species does not turn up relevant prior art.

In reply, as correctly stated by applicant, if the elected species were not found in the prior art, the examination would be extended to other species. Examination of the entire 175 species could hardly be considered few. The search of 175 species would indeed be a burdensome search.

Claim 1-40 and 56-68 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a

nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse.

Status of Claims

Claims 1-68 are pending

Claims 1-40, 43-47, 49-53 and 56-68 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions and species.

Claims 41-42, 48 and 54-55 are under examination.

Specification

The disclosure is objected to because of the following informalities: there is no Seq. ID. Nos. for the sequences listed at Figure 20.

Appropriate correction is required.

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors (typographical, grammatical and idiomatic). Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and

use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 41-42, 48 and 54-55 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

To satisfy a written description requirement for a claimed genus a sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406. A representative number of species means that the species, which are adequately described, are representative of the entire genus. The disclosure of only one species encompassed within a genus adequately describes a claim directed to that genus only if the disclosure indicates that the

applicants have invented species sufficient to constitute the gen[us]. Noelle v. Lederman, 355 F.3d 1343, 1350, 69 USPQ2d 1508, 1514 (Fed. Cir. 2004) (Fed. Cir. 2004).

The specification at page 41, lines 5-10 provides a list of a binding entity. It is ***any small molecule, peptide, or polypeptide*** that can bind to a peptidyl substrate site of kinase. In some embodiments, the binding entities are antibodies. It is apparent from the disclosure general teachings at page 42, line up to 53, line 17 and the Examples that the binding entities are antibodies. There is no description or correlation of the single binding entity, antibodies to the huge scope of the genus drawn to any small molecule, peptide or polypeptide in the specification. It is not apparent from the disclosure whether the conditions and other experimental factors used for antibody can be extrapolated to any binding entity and for the binding entity to still possess the claimed function. The claimed binding entity encompasses a broad number of infinite compounds of any small molecule or peptide or polypeptide of unspecified or undefined structures. In biotechnological invention one cannot necessarily claim a genus after only describing a single species because there may be unpredictability in the results obtained from species other than those specifically described. Attention is directed to Casnellie

reference, (Methods in Enzymology, vol. 200), specifically at page 115. The more unpredictable the art the greater the showing required (e.g. by (representative examples) for both enablement and adequate disclosure. A written description of an invention involving a chemical genus, like a description of a chemical species, requires a precise definition, such as by structure, formula [or] chemical name of the claimed subject matter sufficient to distinguish it from other materials. University of California v. Eli Lilly and Col, 43 USPQ 2d 1398, 1405(1997), quoting Fiers V. Revel, 25 USPQ 2d 1601m 16106 (Fed. Cir. 1993). See also University of Rochester v. G.D. Searle & Co., 68 USPQ2d 1424 (DC WNY 2003).

Applicants, at the time of filing, are deemed to have not invented species sufficient to constitute the genus by virtue of having disclosed a single species when the evidence indicates ordinary artisans could not predict the operability in the invention of any species other than the one disclosed. In re Curtis, 354 F.3d 1347, 1358, 69 USPQ2d 1274, 1282 (Fed. Cir. 2004). One may not preempt an unduly large field by the expedient of making broad prophetic statements in the specification and claim unless the accuracy of such statements is sufficiently supported by well-established chemical principles or by sufficient number of examples.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 42 and 54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "more efficiently" in claim 42 and "less efficiently" in claim 54 is a relative term which renders the claim indefinite. These terms not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

It is not clear as to the measure or basis by which the binding entity is considered as being more or less efficient in binding the different sequences, specifically the elected Seq. ID. 320.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 41-42, 48 and 54-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Polakiewicz et al (2004/00977130 in view of Freeman (USP 5536636) and Laudano et al (USP 6,924,361).

Polakiewicz et al discloses at paragraph [0015] antibodies that selectively bind to IRS-1 and IRS-2 (phosphorylation site, serine) and a compound that modulates phosphorylation of IRS-1 using a detectable reagent, such as the disclosed antibodies, that binds to IRS-1 and/or IRS-2 when phosphorylated at Ser1101 and/or Ser1149, respectively. IRS-1 serine 1101 site is phosphorylated by protein kinase C theta. Polakiewicz et al does not disclose the sequences e.g., Seq. ID. 320 to which the antibodies bind. Freeman discloses at Fig. 2 polypeptide sequence containing the claimed Seq. ID. 320 (e.g., positions 584-595). Freeman discloses in the abstract that the protein tyrosine phosphatase has the SH2 domains. Laudano discloses at col. 11, lines 9-19 antibody binding entity or reagents to other tyr, ser, thr phosphorylation sites that may be used to identify additional prognostic indicators in other cancers or states of

immune system dysfunction. The phosphopeptide-specific antibodies can be used also for screening for inhibitors of specific tyrosine kinases and for identifying the substrate of these kinases, which may provide additional valuable prognostic indications. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the sequences of Freeman as to which the antibodies of Polakiewicz binds differentially to a phosphopeptide and not the non-phosphopeptide. As Laudano discloses at col. 10, line 55 up to col. 11, line 19 the most significant application for tyrosine phosphopeptide-specific antisera will be the measurement of phosphorylation in tissues in order to correlate the level of phosphorylation with disease state to generate improved prognostic indicators to diagnose disease, to monitor disease progression, or to monitor the efficacy of different therapies. The antibodies of this invention were shown to work in cell-based assays and in tissue-based assays. Similar antibody reagents to other tyrosine, serine, threonine or histidine phosphorylation sites that may be used to identify additional prognostic indicators in other cancers or states of immune system dysfunction. The phosphopeptide-specific antibodies of the invention can also be used for screening for inhibitors of specific tyrosine kinases and for identifying the substrates of

these kinases, which may in themselves provide additional, valuable prognostic indicators. The significant application for phosphopeptide determination in different diseases as taught by Laudano would provide the motivation to one having ordinary skill in the art at the time of the invention. Polakiewicz et al at paragraph [0007] suggests a SH2 domain containing proteins that docks to the IRS proteins. Freeman at col. 26, Example 5 discloses or at least suggests differentiation of phospho from non-phosphorylated peptides in leukemia patients.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

A). Kaplan et al disclose the use of SHP-1.

B). Cantley et al describes substrate specificity of a protein kinases.

No claim is allowed.

Any earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is(571) 272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw
August 22, 2005